

**International Conference on Harmonization (ICH)**  
**M2 EWG Meeting - Summary**  
**Tokyo, Japan - 31 August to 03 September 1998**

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**Participants:**

**EU:** Esteban Gonzalez Juarros, Antonia Rana  
**EFPIA:** Gabriele Disselhoff, Mervyn Mitchard (partly), Marc Elbet  
**PhRMA:** Kris Arora, Rick Bowen, Bob Hizer  
**FDA:** Greg Brolund (Rapporteur), Melissa Chapman, George P George, Robin Jones  
**JPMA:** Hitoshi Asano, Yuichi Nagoshi, Keiji Sawamukai, Tohru Uwoi (partly)  
**MHW:** Daisuke Koide, Mihoko Okada, Noburo Takahashi (partly), Kenichi Tamiya,

The tasks accomplished and the decisions agreed are the following:

**Specification for the Electronic CTD**

The Steering Committee endorsed the M2 Electronic CTD Concept Paper. Assignments of M2 EWG members to the different M4 EWGs were confirmed (EFPIA for M4 Quality, JPMA for M4 Safety and PhRMA for M4 Efficacy) and the concept of interaction with the M4 CTD EWGs was established. M2 was also assigned participation in the M4 co-ordination group with the Rapporteur (FDA), EFPIA and JPMA.

The group agreed on a high level work plan for the whole project of the electronic CTD and on a detailed work plan and assignments for the time until the next meeting in March 1999. M2 EWG will produce its deliverables 6 months after the respective deliverables of M4, i.e. a Step 2 document in September 1999 and a Step 4 document in November 2000.

**Specification of the message for electronic transmission of individual case safety reports.**

For the ICSR and Acknowledgement DTD the group agreed on the following:

1. Each ICSR submission will contain as much information as is available at the time of submission (i.e. "complete submission"). This rule will be reflected in version 2.0 DTD by removing the APP/REP/DEL.
2. New or changed information will not be electronically "highlighted" on electronic ICSR submissions. This rule will be reflected in version 2.0 DTD by removing reference to "OLD" attribute.
3. Multiple languages will be supported according to the proposed draft version 2.0 DTD.
4. We have agreed on how to support character sets.
5. Date format, age unit, duration unit, period unit, and time unit will be specified as data items as in version 1.0 in version 2.0.
6. Field sizes will be updated as agreed (see Specification Document).
7. Special characters, such as "<" or "&", will be represented according to the SGML standard.
8. A unique id approach was agreed. A specification describing how to populate A.1.10 was completed.
9. The relationship between Drug and Active Drug Substance entities was agreed. The model will be changed from a one-to-many relationship to a zero-to-many relationship. This will also be reflected in the DTD version 2.0.
10. The data model of the acknowledgement message was agreed. This is noted in the Specification document.
11. Safety report id (safetyreportid) and safety report version (safetyreportversion) will remain optional. These may be required on a regional basis through a guideline.
12. In order to eliminate the mixed content model problem, it was agreed that sequence number entities will be removed.
13. The number of reports contained in a transmission will not be specified in the message header.
14. The doc type reference will be added to the DCL files (as in version 1.0).

15. The DTD and DCL will be tested prior to distribution using James Clark's SP parser. This product is available publically.
16. When modifications are made to the DTD, the organization responsible for typing the changes in the DTD file should indicate their organization name in the comments area (i.e. JPMA or FDA, etc.).

The next M2 meeting will take place on March 8 – 13, 1999 as proposed for the ICH Steering Committee meeting.